REMARKS

In the Final Rejection, the Examiner rejects Claims 12-17 and 24-27 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. This rejection is respectfully traversed.

In particular, the Examiner objects to the amendment to Claim 12 in Amendment B filed on February 11, 2005 of "wherein said second and third lumens are return lumens which receive the treating element at the distal end to return the treating elements from the distal end of the catheter to the proximal end of the catheter." The Examiner contends that the addition of the language that the second and third lumens are return lumens which receive the treating element at the distal end to return the treating elements from the distal end of the catheter to the proximal end of the catheter is new matter which is not supported by the specification as filed.

In order to clarify the meaning of Claim 12, Applicants are amending Claim 12 to describe the second and third lumens as follows: "wherein said second and third lumens are fluid lumens which are able to move fluid from the distal end of the catheter to the proximal end of the catheter to advance the treating element to the distal end of the catheter and are able to move fluid from the proxmial end to the distal end of the catheter to return the treating elements from the distal end of the catheter to the proximal end of the catheter.

As stated on page 3 of the specification of the present application, a principal object of the present invention is to improve the device described in US 5,899,882; USSN 08/936,058 (now US 6,013,020) and USSN 09/304,752 (now US 6,261,219)[1] by providing "a transfer device and catheter assembly that has additional safeguards to protect the patient and user for unintended exposure to

[1]US 5,899,882 and US 6,013,020 are already of record in this application. Applicants are including US 6,261,219 in an IDS enclosed herewith.

radiation." Page 2 describes these patents and applications as being directed to an apparatus comprising a catheter and a transfer device for facilitating advancement and retrieval of radioactive treatment/ treating elements or seeds along the catheter to and from the treatment site. Lns. 16-28. Page 3 discusses the movement of the treating elements to and from the distal end of the catheter and the heightened need for safety to prevent any unintended exposure of the patient to radioactivity. Lns. 5-10.

The Summary of the Invention of the present application discusses "circulating fluid through a fluid path defined by the transfer device and associated catheter." Page 4, lns. 8-9. Page 5, lns. 26-27 discuss the embodiment of the present application with one lumen to slidingly receive a treating element and being in fluid communication with two lumens at the distal end for the return of fluid, and a fourth lumen for a guidewire.

Page 12 of the specification discusses that in the send mode, fluid is directed into the catheter through the source delivery lumen and out of the catheter through the fluid return lumen, and that in the return mode, the direction of flow of the fluid is reversed. The reversal of the fluid flow for returning the treating elements is again discussed on page 24, lns. 23-28 of the specification.

Page 26, lns. 4-10 of the specification state:

> "The transfer device 10 can be connected to any of the catheters that are disclosed in the patent and applications previously incorporated by reference. Additionally, catheters 140, 142, having the cross-sections illustrated in Figures 23-24, may be used to deliver the treatment elements to a selected site within a patient."

US 5,899,882 (incorporated by reference) discusses the return lumen as communicating with the principal lumen to provide a closed circulation path for the liquid that dispatches and retrieves the treating elements. Col. 10, lns. 5-11. Col. 10 also discusses that for advancing the treating elements to the distal end of the catheter, fluid is forced into the principal lumen which forces the

treating elements to the distal end of the catheter. As liquid moves along the principal lumen in the distal direction, it displaces an equal amount of liquid out of the return lumen. For retrieval of the treating elements, the process is reversed, forcing liquid in the distal direction in the return lumen and moving the treating elements in a proximal direction along the principal lumen to the central bore of the transfer device.

As explained above, the device of the '899 patent is incorporated by reference into the present application, and the catheter of the present application works in a similar manner, except that the present invention is an improvement thereon, having 4 lumens with two being "return" lumens. Such a structure improves fluid flow, and allows the user to more quickly introduce and remove the radioactive treating elements from the patient which protects the patient from unintended exposure to radiation.

Hence, it is respectfully submitted that amended independent Claim 12 is clearly supported by the present application and includes no new matter. Accordingly, it is respectfully requested that this rejection be withdrawn.

Applicants also wish to expand on their prior arguments regarding the patentability of the claimed invention over the cited references, in light of the clarifying amendments herein to Claim 12.

Claim Rejections - 35 USC §102

In the prior Office Action, the Examiner rejected Claims 12 and 15-17 under 35 USC §102(e) as being anticipated by Saab (US 5,624,392). This rejection is still respectfully traversed.

The present application is directed to a catheter for the delivery of radiation treating elements to a selected location within the intraluminal passageways. With such a device, there is a heightened

concern for safety to prevent any unintended exposure of either the patient or the user to radioactivity. Accordingly, the present application is directed to safeguards to protect the patient and user from unintended or prolonged exposure to radiation.

One of these safeguards is a catheter having first, second, third and fourth lumens, as recited in Claim 12 of the present application. As explained in the specification (e.g. page 5, lns. 21-28; page 26, ln. 12- page 27, ln. 15) and shown in the drawings (see e.g. Figs. 23A, 23B and 24) of the present application, one lumen is sized to slidingly receive the treating element for advancing the treating element from the proximal end of the catheter to the distal end of the catheter (and to prevent the treating element from exiting the first lumen to outside the catheter at the distal end of the catheter) and for return of the treating elements to the proximal end of the catheter and out of the patient. By having one lumen for advancing the treating elements from the proximal end of the catheter to the treatment site at the distal end of the catheter and retrieval of the treating elements, the amount of radiation given to the patient, where the radiation treatment occurs and the length of exposure of the radiation to the treatment site (i.e. the selected location) can be controlled.

However, it is desirable to have the radioactive treating elements get to the distal end of the catheter, and the treatment area, as quickly as possible to minimize exposure of healthy tissue to radiation. Further, once the desired period for treatment (and exposure to radiation) is completed, it is highly desirable to remove the treating elements from the patient's body as quickly as possible. Accordingly, the catheter of the present application was designed with two return lumens in fluid communication with the first lumen at the distal end thereof, to quickly force the treating elements from the proximal to the distal end for treatment, and to force the treating elements from the distal end of the catheter to the proximal end of the catheter, which is outside the patient's body, once treatment is finished (see e.g. 150 in Figs. 23A and 23B and 158 in Fig. 24; page 26, ln. 12 - page

27, ln. 15). In this way, the treating elements are quickly moved to the treatment area and removed from the body, limiting the patient's exposure to the radiation, especially at non-treatment or non-selected locations.[2]

In contrast to the catheter of the present application, Saab is directed to a heat transfer catheter. With such a catheter, a major concern is that for the heat transfer fluid (which is at a different temperature than body temperature, either colder or hotter), at locations distal to the proximal point of the catheter where the fluid is introduced, the temperature of the fluid tends to approach the internal body temperature. Further, any temperature difference, even that at the proximal end, exists for only a relatively short time until the fluid at every point along the catheter is heated or cooled to body temperature, which would render the attempted treatment with such fluid worthless (see e.g. col. 4, lns. 46 - 67). Therefore, it is desirable to have the heat transfer fluid reach the treatment area as quickly as possible before the fluid heats/cools to body temperature. Further, since the fluid quickly heats/cools to internal body temperature after treatment, it is not necessary to quickly remove it from the body.

Accordingly, in the Saab embodiment cited by the Examiner in the Office Action (e.g. Fig. 10, col. 16), there are two lumens (108 and 110) for introducing fluid to the catheter and transferring it to the distal end of the catheter and one fluid outlet lumen (114). This arrangement in the cited reference is considered advantageous for introducing fluids at different temperatures. However, the fluid in Saab is only able to flow in a single direction, i.e. two inlet and only single return lumen. The Saab device is not created to have fluid communication in two directions so as to enable reverse fluid flow to remove treating elements from the body. Hence, the device in Saab is very different

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[2]There is also a fourth lumen open at the distal end and sized to receive a guidewire.

and works in a very different manner than the catheter claimed in independent Claim 12 of the present application.

The Examiner also contends that Saab discloses the catheter of dependent Claim 15. Applicants disagree. Claim 15 is directed to a catheter having different stiffness and flexibility at the proximal and distal ends, a smaller cross-sectional shape for the distal end and the distal end of the catheter having a non-circular cross-sectional shape. The Examiner cites Fig. 10 and the discussion at col. 16, lns. 59-67 and col. 17, lns. 1-3 of Saab as showing this feature. However, none of those sections show or suggest that the shape of the catheter is non-circular (see Fig. 10 which is round), as in Claim 15.

Therefore, Saab fails to disclose or suggest the catheter of independent Claim 12 or those claims dependent thereon, and these claims are patentable thereover. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claim Rejections - 35 USC §103

Claims 13 and 14

The Examiner also rejects Claims 13 and 14 under 35 USC §103(a) as being unpatentable over Saab in view of Machold et al. (US 4,976,720). This rejection is respectfully traversed.

These claims are dependent claims. Therefore, for at least the reasons discussed above for independent Claim 12, these dependent claims are also patentable over the cited references. Accordingly, it is respectfully requested that this rejection be withdrawn.

Claims 12 and 15-17

The Examiner also rejects Claims 12 and 15-17 under 35 USC §103(a) as being unpatentable

over Waksman et al. (US 5,683,345) in view of Saab. This rejection is respectfully traversed.

As explained above, independent Claim 12 is directed to a catheter with four lumens, two of which are return or fluid lumens.

In contrast, Waksman only describes a single "return" lumen 204 (and only 3 lumens in the catheter, not four as recited in Claim 12, the third lumen being a guidewire lumen). See e.g. Col. 17 and 18, in Waksman. There is nothing in the specification in the reference to indicate that there are two return lumens nor four lumens in all.

Further, as explained above, while Saab discloses 4 lumens, it only discloses a single return lumen and does not disclose or suggest the two fluid lumens of Claim 12 which are able to have fluid flow in both directions for quickly forcing treating elements to the distal end and then back to the proximal end of the source lumen for treatment. Hence, even if it was proper to combine these two references (which Applicants do not admit), the combination thereof would still fail to disclose or suggest the catheter of independent Claim 12 having four lumens with the two claimed fluid lumens.

Additionally, as the Examiner admits, Waksman does not teach or suggest the catheter of Claim 15. While the Examiner cites Saab as showing such a catheter, as explained above, Saab fails to disclose a catheter with the features of Claim 15, especially one having a non-circular cross-sectional shape of the distal end of the catheter.

Therefore, it is respectfully requested that this rejection be withdrawn.

Information Disclosure Statement

Applicants are filing an information disclosure statement (IDS) herewith. It is respectfully requested that prior to the issuance of any further action, this IDS be entered and considered. If any fee should be due for this IDS please charge our deposit account 50/1039.

Conclusion

Therefore, for at least the above-stated reasons, it is respectfully submitted that the present application is in a condition for allowance and should be allowed.

If any fee is due for this amendment, please charge our deposit account 50/1039.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,

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